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Kathy Hinckley

PATENT

Applicant:	George Martinez
Serial No.:	10/631,981
Filed:	July 31, 2003
Title:	**THREE ELEMENT COAXIAL VASO-OCCLUSIVE DEVICE**
Examiner:	Elizabeth Houston
Group Art Unit:	3731
Confirmation No.:	2212
Atty. Docket No.:	388700-612-11-PA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

APPEAL BRIEF UNDER 37 CFR § 41.37

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Final Office Action mailed March 10, 2009, please consider the Appeal Brief contained herein. It is believed that this Appeal Brief addresses all outstanding issues; that entry of this Appeal Brief is proper; and that the preparation and mailing of an Examiner's Answer is now in order.

The Commissioner is hereby authorized to charge payment of the $540.00 fee for filing of this Appeal Brief and the two-month extension of time fee of $490.00 to the credit card specified during the EFS process. The Commissioner is authorized to charge any additional filing fees or credit any overpayment to Deposit Account No. 50-2809.

REAL PARTY IN INTEREST

The real party in interest is MicroVention, Inc., a Delaware corporation having a place of business at 1311 Valencia Avenue, Tustin, California 92780. MicroVention, Inc. is the Assignee of all rights in the application.

RELATED APPEALS AND INTERFERENCES

There are currently no appeals or interferences known to the appellant, the appellant's legal representative, or assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1-67 are currently pending and of these claims, claims 1,14, 29, 40, 52, 66 and 67 are independent. Claims 1-67 are rejected based on prior art. Claims 1-67 are currently being appealed.

STATUS OF AMENDMENTS

No amendments have been filed subsequent to final rejection. The claims as they are currently entered are presented in the Appendix of this document.

SUMMARY OF CLAIMED SUBJECT MATTER

In accordance with 37 C.F.R. 41.37(c)(1)(v) the subject matter of the independent claims 1, 14, 29, 40, 52, 66 and 67 and dependent claims 2, 4, 9, 19, 24, 25, 31, 36, 43, 48, 57 and 62 is concisely explained below. It is believed that none of these claims includes means plus function or step plus function wording.

The subject matter as defined in claim 1 involved in this appeal relates to a vaso-occlusive implant (Fig. 1). The implant includes an elongate, flexible, filamentous inner element (para 0020-0021; page 6 line 14 – P page age 7 line 5[1]). A non-metallic expansile intermediate element (para 0023-0034; page 7 line 6 – page 12 line 15) coaxially surrounds the inner element and is in intimate contact therewith substantially along the length of the inner member. The expansile intermediate element is capable of expanding at a controlled rate to fill an aneurysm (para 0031-0033; page 11 line 1 –

[1] Note that paragraph numbers reference the published application while page and line numbers reference the Application as filed.

page 12 line 3). An outer element coaxially surrounds the intermediate element and is in intimate contact therewith (para 0035-0036; page 12 line 16 – page 13 line 9). The outer element defines a gap or opening through which the intermediate element is exposed (para 0037-0038; page 13 line 10 – page 14 line 2).

The subject matter as defined in claim 14 involved in this appeal relates to a vaso-occlusive implant that includes first, second, and third elongate, flexible elements arranged coaxially (Fig. 1). The first element is a filamentous inner element (para 0020-0021; page 6 line 14 – P page age 7 line 5). The second element is an expansile intermediate element (para 0031-0033; page 11 line 1 – page 12 line 3). The third element is an outer element having an opening or gap through which the intermediate element swells at a controlled rate to fill an aneurysm (para 0035-0036; page 12 line 16 – page 13 line 9). At least one of the inner and intermediate elements is made at least in part of a non-metallic biocompatible material (para 0031-0033; page 11 line 1 – page 12 line 3).

The subject matter as defined in claim 29 involved in this appeal relates to a vaso-occlusive device (Fig 1) that includes an elongate, flexible, filamentous microcoil inner element (para 0020-0021; page 6 line 14 – P page age 7 line 5). An intermediate element coaxially surrounds the inner element and is in intimate contact therewith and is formed essentially of an expansile polymer capable of expanding at a controlled rate to fill an aneurysm (para 0031-0033; page 11 line 1 – page 12 line 3). A substantially non-expansile outer element coaxially surrounds the intermediate element and is in intimate contact therewith to define a gap or opening through which the intermediate element is exposed (para 0035-0036; page 12 line 16 – page 13 line 9). The intermediate element, when expanded, protrudes through the gap or opening in the outer element and assumes a configuration with an undulating, convexly-curved outer surface defining a chain of arcuate segments, each having a diameter significantly greater than the diameter of the outer element (para 0037-0038; page 13 line 10 – page 14 line 2).

The subject matter as defined in claim 40 involved in this appeal relates to a vaso-occlusive device (Fig. 1) that includes an elongate, flexible, filamentous inner element (para 0020-0021; page 6 line 14 – P page age 7 line 5). A non-metallic expansile intermediate element coaxially surrounds the inner element and is in intimate contact therewith (para 0031-0033; page 11 line 1 – page 12 line 3). The expansile intermediate element is capable of expanding at a controlled rate to fill an aneurysm (para 0031-0033; page 11 line 1 – page 12 line 3). An outer element coaxially surrounds the intermediate element and is in intimate contact therewith, the outer element defining a gap or opening through which the intermediate element is exposed (para 0035-0036; page 12 line 16 – page 13 line 9). The inner element has proximal and distal ends (Fig. 1), and the outer element comprises an open-wound helical coil portion extending between proximal and distal end sections that are respectively attached to the inner element adjacent to the proximal and distal ends of the inner element, wherein the open-wound portion defines the gap or opening (para 0037-0038; page 13 line 10 – page 14 line 2).

The subject matter as defined in claim 52 involved in this appeal relates to a vaso-occlusive device that includes a first, second, and third elongate, flexible elements arranged coaxially (Fig. 1). The first element is a filamentous inner element (para 0020-0021; page 6 line 14 – P page age 7 line 5). The second element is an expansile intermediate element capable of expanding at a controlled rate to fill an aneurysm (para 0031-0033; page 11 line 1 – page 12 line 3). The third element is an outer element having an opening or gap through which the intermediate element is exposed (para 0035-0036; page 12 line 16 – page 13 line 9). The at least one of the inner and intermediate elements is made at least in part of a non-metallic biocompatible material (para 0031-0033; page 11 line 1 – page 12 line 3). The inner element has proximal and distal ends (Fig. 1). The outer element comprises an open-wound helical coil portion extending between proximal and distal end sections that are respectively attached to the inner element adjacent to the proximal and distal ends of the inner element, wherein

the open-wound portion defines the opening or gap (para 0037-0038; page 13 line 10 – page 14 line 2).

The subject matter as defined in claim 66 involved in this appeal relates to a vaso-occlusive device (Fig. 1) that includes an expansile first member capable of expanding at a controlled rate to fill an aneurysm having an expanded diameter (para 0031-0033; page 11 line 1 – page 12 line 3). A second member is helically surrounding the first member, the second member having a diameter smaller than the expanded diameter of the first member, such that portions of the first member expand through coils of the second member when the device is released in a vasculature (para 0035-0036; page 12 line 16 – page 13 line 9).

The subject matter as defined in claim 67 involved in this appeal relates to a vaso-occlusive device (Fig. 1) that includes an open-coiled element (para 0035-0036; page 12 line 16 – page 13 line 9). An expansile element capable of expanding at a controlled rate to fill an aneurysm and having a first state and a second state wherein: in said first state said expansile element does not extend through openings between coils of the open-coiled element; in said second state said expansile element is expanded through said openings between said coils of the open-coiled element (para 0031-0033; page 11 line 1 – page 12 line 3).

The subject matter as defined in claim 2 involved in this appeal relates to a microcoil (Fig. 1, element 11) made of a biocompatible material selected from the group consisting of metal wire and polymeric filament (para 0020-0021; page 6 line 14 – P page age 7 line 5).

The subject matter as defined in claim 4, 19, 25, 31, 36, 43 and 57 involved in this appeal relates to an open-wound, helically-coiled portion (Fig. 1-4, element 13) that defines the gap or opening through which the intermediate element (Fig. 3-4, element 12) is exposed.

The subject matter as defined in claim 9, 24, 48 and 62 involved in this appeal relates to an intermediate element (element 12), when expanded, extends through the

openings of the outer element to form an exterior surface having an undulating configuration defining a chain of convexly-curved arcuate segments (Figs 3 and 4).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection to be reviewed on appeal is the Examiner's rejection of claims 1-67 under 35 U.S.C. Section 103(a). The Examiner contends that these claims are unpatentable over U.S. Publication No. 2002/0169473 to Sepetka ("*The Sepetka Publication*") in view of U.S. Patent No. 7,006,904 to Rosenthal ("*The Rosenthal Patent*") in further view of PCT Pub. No. WO 98/01421 to Kopecek ("*The Kopecek Publication*").

ARGUMENT

I. INDEPENDENT CLAIMS 1, 14, 29, 40, 52, 66 AND 67

The Examiner argues that *The Sepetka Publication* in view of *The Rosenthal Patent* and *The Kopecek Publication* will result in the invention as recited in independent claims 1, 14, 29, 40, 52, 66 and 67. *The Sepetka Publication* is directed to a stent composed of two oppositely coiled coil members 352 (see Fig. 64 below) that can optionally have a drug coating on them. Secondary windings 354 are wrapped around the shape created by both coil members 352.

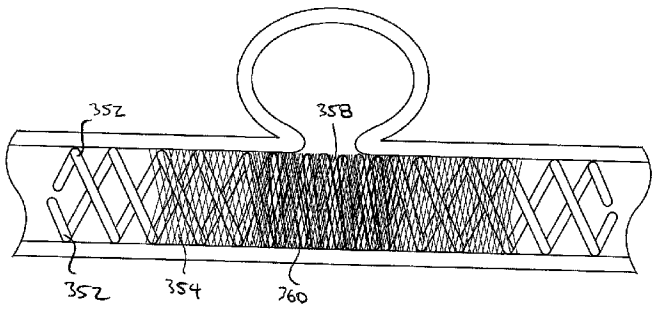
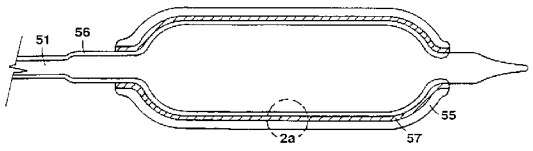


FIG 64

The Rosenthal Patent is directed to an expandable, porous balloon having a hydrogel coating (see figure below). Drugs are located in the hydrogel coating and are released when the hydrogel reacts with certain physiological conditions or a triggering agent. The hydrogel reaction and drug release can result in a slight contraction or expansion of the hydrogel layer.



The Kopecek Publication discloses a hydrogel for use in delivering a drug to the colon. Once ingested, the hydrogel undergoes a reaction that is timed to release its drugs at a desired point in a patient's digestive tract. More specifically, the Kopecek hydrogel is configured such that a predetermined pH triggers when expansion (and therefore drug delivery) begins.

Even if all cited references are combined together, they do not show or make obvious every element recited in independent claims 1, 14, 29, 40, 52, 66 and 67. For example, these claims recite (with different language) an expansile intermediate element capable of expanding or swelling at a controlled rate to fill an aneurysm. This allows the implant of the claims to be inserted into an aneurysm, and then expanded at a controlled rate to fill the aneurysm, thereby treating it.

First, the device shown in Fig. 64 of *The Sepetka Publication* cannot be positioned within an aneurysm and therefore cannot fill an aneurysm as asserted by the Examiner. Its size, shape, configuration, and flexibility would prevent any kind of entry into the aneurysm, as is obvious from even a cursory review of Fig. 64 above.

Further, it should be noted that aneurysms typically have a distended shape formed by a layer of tissue much thinner and more fragile than a healthy blood vessel. Devices or materials that enter an aneurysm must therefore be highly flexible, soft and smooth. In contrast, expandable stents, such as the Sepetka device, are relatively stiff, produce a great deal of outward, expansive force intended for the interior of a vessel

and have protruding wire members for pressing into the vessel tissue and anchoring it in place. Attempting to insert the *Sepetka* device would almost certainly rupture the aneurysm, thereby killing the patient. Similarly, *The Rosenthal Patent* and *The Kopecek Publication* fail to show any structure that would make up for this deficiency since they fail to show an implantable device of any kind.

Second, none of the cited references teach that the hydrogel expands at a controlled rate to fill an aneurysm as claimed. The Examiner admits that *The Rosenthal Patent* and *The Sepetka Publication* fail to teach hydrogel expansion at a controlled rate. Instead, the Examiner relies on *The Kopecek Publication*, which discloses that its hydrogel delivers drugs in a controlled reaction to time their release at a specific point in the intestinal tract of a patient. As with *The Rosenthal Patent*, the *Kopecek* hydrogel releases its drugs by swelling.

More specifically, the *Kopecek* hydrogel controls its drug release (and swelling) by initially providing labile N,O-diacylhydroxylamine moieties in the hydrogel that are stable in the acidic medium of the stomach but that are susceptible to hydrolysis at the intestinal pH. Upon hydrolysis, ionized –cooh groups attached to the polymer network are generated and swelling occurs as the hydrogel reaches the colon where degradation occurs by the azoreductase cleaveage of the aromatic azo cross-linking agent. In other words, the hydrogel protects the drug through the acidic environment of the stomach (about a pH of 1-4), then swells at a controlled rate in the higher pH environment of the small intestine (about a pH of 6-7) and is enzymatically degraded in the colon thereby releasing the drug into the colon. Hence, the controlled rate of the *Kopecek* hydrogel is narrowly tailored for the specific series of environmental changes that occur within the intestinal tract of a patient.

In contrast, an aneurysm contains blood and therefore has a relatively narrow and constant pH range of about 7.35 and 7.45. Additionally, the blood lacks the enzymatic activity of the colon that causes azoreductase cleaveage of the aromatic azo cross-linking agent, as occurs with the *Kopecek* hydrogel. Therefore, the use of the *Kopecek* hydrogel would not provide the desired expansion characteristics for

expanding at a controlled rate to fill an aneurysm. Even if the *Kopecek* hydrogel was somehow triggered to expand within the blood of an aneurysm, which it is not clear would happen, it would not expand in a controlled manner since it would be located in an environment different from that of an intestinal tract (e.g., different pH and different enzymes).

Third, *The Rosenthal Patent* does not teach the use of a hydrogel in a manner capable of filling an aneurysm. As previously described, *The Rosenthal Patent* uses a thin layer of hydrogel only to deliver a drug. A byproduct of the drug delivery is the slight contraction or expansion of the hydrogel. Even if the *Sepetka* device could be positioned within an aneurysm (which it cannot), the *Rosenthal* hydrogel layer would be insufficient to fill the aneurysm.

Fourth, none of the cited references teach or even suggest the use of a swellable or expandable coating on an implant device (i.e., a device left in a patient).

Fifth, none of the cited references teach an intermediate element that swells at a controlled rate. The Examiner argues that *The Kopecek Publication* teaches such swelling. While in at least one location (e.g., pg 11, lines 1-3), *The Kopecek Publication* states that hydrogel swelling is "chemically controlled", a closer review of this reference, as best understood, reveals that this "control" is directed simply to a triggering pH that causes the hydrogel to begin expanding. In other words, this reference discloses when expansion starts, not the rate at which expansion is controlled as claimed. For example, page 11, line 33 through page 12 line 2 states, "In this configuration the hydrogel contains labile N,O-diacylhydroxylamine moieties that are stable in acidic medium, such as encountered in the stomach (pH 1-4) but that are susceptible to hydrolysis above approximately pH 6.5." If the rate of swelling is not controlled, a user may have too little or too much time before swelling is completed, which may lead to serious medical complications. For example, an implant may expand too quickly in a patient during delivery, preventing a user from positioning the implant at a target treatment location and possibly introducing serious complications inside the patient.

Finally, the Examiner has failed to make a proper prima facie case of obviousness. The Examiner states that "all of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions…" As set forth above, the cited references do not contain all claim elements as asserted by the Examiner. With all due respect, the Examiner's statement could only be true if claim language in the rejected claims was ignored. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

> "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396. However, the Examiner's rationale for the combination of elements from the cited references, as partially quoted above, appears to be conclusory. At best, the Examiner argues that the combination of the cited references would have provided "predictable results to one of ordinary skill in the art at the time of the invention, namely a way of delivering a drug in a controller manner via the use of hydrogel and triggering mechanism."

With all due respect to the Examiner, this rationale reveals a basic misunderstanding about the present invention as recited in the claims. The present invention as differently recited in the claims relates to expanding hydrogel at a controlled rate to fill an aneurysm. Drug delivery is not mentioned in the claims, or the specification. Hence, the basic premise of the Examiner's prima facie case of obviousness is flawed. It should be noted that "if the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness," MPEP Section 2142.

> The present invention as recited in these claims allows for functionality and advantages not seen in the cited prior art. For example, paragraph **[0014]** of the present published applications states:

> **[0014]** The invention thus provides a microcoil vaso-occlusive device with an expansile element that allows the device to embolize very efficiently a wide variety of vascular abnormalities, e.g., aneurysms of a wide variety of shapes, sizes, and locations, and yet that exhibits enhanced pushability and trackability as compared to the prior art.

For at least these reasons, claims 1, 14, 29, 40, 52, 66 and 67 and their dependent claims are novel and nonobvious over the cited references.

II. DEPENDENT CLAIMS

The pending dependent claims depend on the independent claims and therefore are novel and nonobvious over the cited references for at least the reasons argued for the independent claims above.

While the Examiner has official rejected the dependent claims, the most recent Final Office Action dated March 10, 2009 (as best understood by the undersigned), fails to address the contents of many of these claims[2]. The undersigned further failed to find a basis for rejection for many of these dependent claims in the cited prior art. It should be understood that the Examiner is required to consider the language of the dependent claims, provide a rational underpinning for a combination of the references and otherwise make a proper *prima facie* case of obviousness. Hence, the Examiner has failed to make a *prima facie* case of obviousness. "If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness," MPEP Section 2142.

The following discussion of example dependent claims further emphasizes the elements that the Examiner failed to discuss and were not found in the cited prior art. However, these examples are not intended to provide an exhaustive list of claim elements since the burden of proof rests with the Examiner to make a proper *prima facie* case of obviousness.

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[2] Since the Examiner failed to individually reference the dependent claims in the most recent Final Office Action, it is unclear exactly which elements of the prior art the Examiner is relying on for the rejections of many of the dependent claims.

Claim 2

Claim 2 recites that the inner element comprises a microcoil made of a biocompatible material selected from the group consisting of metal wire and polymeric filament. While the Examiner has rejected this claim, the most recent Final Office Action dated March 10, 2009 (as best understood by the undersigned) fails to provide any discussion of a microcoil. Similarly, the undersigned was unable to find reference to a microcoil in any of the cited prior art. Hence, the Examiner has failed to make a *prima facie* case of obviousness.

Claims 9, 24, 48 and 62

Claims 9, 24, 48 and 62 recite that the intermediate element, when expanded, extends through the openings of the outer element to form an exterior surface having an undulating configuration defining a chain of convexly-curved arcuate segments. While the Examiner has rejected this claim, the most recent Final Office Action dated March 10, 2009 (as best understood by the undersigned) fails to provide any discussion of this undulating configuration as recited. Similarly, the undersigned was unable to find reference to such a configuration as recited in any of the cited prior art. Hence, the Examiner has failed to make a *prima facie* case of obviousness.

Claims 4, 19, 25, 31, 36, 43 and 57

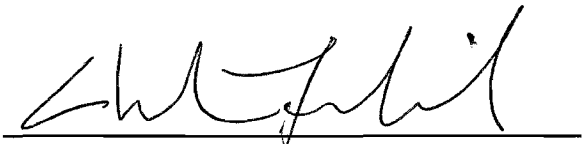
Claims 4, 19, 25, 31, 36, 43 and 57 recites that the outer element includes an open-wound, helically-coiled portion that defines the opening or gap through which the intermediate element swells. While the Examiner has rejected this claim, the most recent Final Office Action dated March 10, 2009 (as best understood by the undersigned) fails to provide any discussion of these gaps through which the intermediate element swells as recited. Similarly, the undersigned was unable to find reference to such a configuration as recited in any of the cited prior art. Hence, the Examiner has failed to make a *prima facie* case of obviousness.

IV. CONCLUSION

For at least all the reasons stated herein, it is submitted that the Examiner's rejection is erroneous. As a result, the Applicant's seek a reversal of the Examiner's rejection on this appeal. Reversal is hereby affirmatively requested.

Respectfully submitted,

Dated: November 4, 2009



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CLAIMS APPENDIX

Listing of Claims

1. (Previously Presented) A vaso-occlusive implant, comprising:

an elongate, flexible, filamentous inner element;

a non-metallic expansile intermediate element coaxially surrounding the inner element and in intimate contact therewith substantially along the length of the inner member, said expansile intermediate element capable of expanding at a controlled rate to fill an aneurysm; and

an outer element coaxially surrounding the intermediate element and in intimate contact therewith, the outer element defining a gap or opening through which the intermediate element is exposed.

2. (Previously Presented) The vaso-occlusive implant of claim 1, wherein the inner element comprises a microcoil made of a biocompatible material selected from the group consisting of metal wire and polymeric filament.

3. (Previously Presented) The vaso-occlusive implant of claim 1, wherein the intermediate element includes an expansile polymeric material.

4. (Previously Presented) The vaso-occlusive implant of claim 1, wherein the outer element includes an open-wound, helically-coiled portion that defines the gap or opening through which the intermediate element is exposed.

5. (Previously Presented) The vaso-occlusive implant of claim 1, wherein the inner element has proximal and distal ends, and wherein the device further comprises a coupling element attached to the proximal end.

6. (Previously presented) The vaso-occlusive implant of claim 3, wherein the expansile polymeric material consists essentially of a hydrogel.

7. (Previously Presented) The vaso-occlusive implant of claim 6, wherein the hydrogel is of a type that expands in response to a change in an environmental parameter.

8. (Previously Presented) The vaso-occlusive implant of claim 7, wherein the environmental parameter is selected from the group consisting of temperature and pH.

9. (Previously Presented) The vaso-occlusive implant of claim 1, wherein the intermediate element, when expanded, extends through the openings of the outer element to form an exterior surface having an undulating configuration defining a chain of convexly-curved arcuate segments.

10. (Previously Presented) The vaso-occlusive implant of claim 1, wherein the inner element has proximal and distal ends, and wherein the outer element comprises an open-wound helical coil portion extending between proximal and distal end sections that are respectively attached to the inner element adjacent to the proximal and distal ends of the inner element, wherein the open-wound portion defines the gap or opening.

11. (Previously Presented) The vaso-occlusive implant of claim 10, wherein the proximal end section of the outer element includes a close-wound helical coil section.

12. (Previously Presented) The vaso-occlusive implant of claim 10, wherein each of the proximal and distal end sections of the outer element includes a close-wound helical coil section.

13. (Previously Presented) The vaso-occlusive implant of claim 11, further comprising a coupling element attached to the proximal end of the inner element and to the proximal end section of the outer element.

14. (Previously Presented) A vaso-occlusive implant comprising:

first, second, and third elongate, flexible elements arranged coaxially, wherein the first element is a filamentous inner element, the second element is an expansile intermediate element, and the third element is an outer element having an opening or gap through which the intermediate element swells at a controlled rate to fill an aneurysm, and wherein at least one of the inner and intermediate elements is made at least in part of a non-metallic biocompatible material.

15. (Previously Presented) The vaso-occlusive implant of claim 14, wherein the biocompatible material includes a bioactive agent.

16. (Previously Presented) The vaso-occlusive implant of claim 14, wherein the biocompatible material includes a therapeutic compound.

17. (Previously Presented) The vaso-occlusive implant of claim 14, wherein the inner element comprises a microcoil made of a biocompatible material selected from the group consisting of metal wire and polymeric filament, and wherein the intermediate element is formed of a biocompatible polymeric material

18. (Previously Presented) The vaso-occlusive implant of claim 14, wherein the intermediate element includes an expansile polymeric material.

19. (Previously Presented) The vaso-occlusive implant of claim 14, wherein the outer element includes an open-wound, helically-coiled portion that defines the opening or gap through which the intermediate element swells.

20. (Previously Presented) The vaso-occlusive implant of claim 14, wherein the inner element has proximal and distal ends, and wherein the device further comprises a coupling element attached to the proximal end.

21. (Previously Presented) The vaso-occlusive implant of claim 18, wherein the expansile polymeric material consists essentially of a hydrogel.

22. (Previously Presented) The vaso-occlusive implant of claim 21, wherein the hydrogel is of a type that expands in response to a change in an environmental parameter.

23. (Previously Presented) The vaso-occlusive implant of claim 22, wherein the environmental parameter is selected from the group consisting of temperature and pH.

24. (Previously Presented) The vaso-occlusive implant of claim 14, wherein the intermediate element, when expanded, extends through the opening or gap of the outer element to form an exterior surface having an undulating configuration defining a chain of convexly-curved arcuate segments.

25. (Previously Presented) The vaso-occlusive implant of claim 14, wherein the inner element has proximal and distal ends, and wherein the outer element comprises an open-wound helical coil portion extending between proximal and distal end sections that are respectively attached to the inner element adjacent to the proximal and distal ends of the inner element, wherein the open-wound portion defines the opening or gap.

26. (Previously Presented) The vaso-occlusive implant of claim 25, wherein the proximal end section of the outer element includes a close-wound helical coil section.

27. (Previously Presented) The vaso-occlusive implant of claim 25, wherein each of the proximal and distal end sections of the outer element includes a close-wound helical coil section.

28. (Previously Presented) The vaso-occlusive implant of claim 26, further comprising a coupling element attached to the proximal end of the inner element and to the proximal end section of the outer element.

29. (Previously Presented) A vaso-occlusive device, comprising:

an elongate, flexible, filamentous microcoil inner element;

an intermediate element coaxially surrounding the inner element and in intimate contact therewith and formed essentially of an expansile polymer capable of expanding at a controlled rate to fill an aneurysm; and

a substantially non-expansile outer element coaxially surrounding the intermediate element and in intimate contact therewith, the outer element defining a gaps or opening through which the intermediate element is exposed;

wherein the intermediate element, when expanded, protrudes through the gap or opening in the outer element and assumes a configuration with an undulating, convexly-curved outer surface defining a chain of arcuate segments, each having a diameter significantly greater than the diameter of the outer element.

30. (Original) The vaso-occlusive device of claim 29, wherein the microcoil is made of a biocompatible material selected from the group consisting of metal wire and polymeric filament.

31. (Original) The vaso-occlusive device of claim 29, wherein the outer element includes an open-wound, helically-coiled portion that defines the gap or opening through which the intermediate element is exposed.

32. (Original) The vaso-occlusive device of claim 29, wherein the inner element has proximal and distal ends, and wherein the device further comprises a coupling element attached to the proximal end.

33. (Original) The vaso-occlusive device of claim 29, wherein the expansile polymeric material consists essentially of a hydrogel.

34. (Original) The vaso-occlusive device of claim 33, wherein the hydrogel is of a type that expands in response to a change in an environmental parameter.

35. (Original) The vaso-occlusive device of claim 34, wherein the environmental parameter is selected from the group consisting of temperature and pH.

36. (Original) The vaso-occlusive device of claim 29, wherein the inner element has proximal and distal ends, and wherein the outer element comprises an open-wound helical coil portion extending between proximal and distal end sections that are respectively attached to the inner element adjacent to the proximal and distal ends of the inner element, wherein the open-wound portion defines the gap or opening.

37. (Original) The vaso-occlusive device of claim 36, wherein the proximal end section of the outer element includes a close-wound helical coil section.

38. (Original) The vaso-occlusive device of claim 36, wherein each of the proximal and distal end sections of the outer element includes a close-wound helical coil section.

39. (Original) The vaso-occlusive device of claim 37, further comprising a coupling element attached to the proximal end of the inner element and to the proximal end section of the outer element.

40. (Previously Presented) A vaso-occlusive device, comprising:

an elongate, flexible, filamentous inner element;

a non-metallic expansile intermediate element coaxially surrounding the inner element and in intimate contact therewith, said expansile intermediate element capable of expanding at a controlled rate to fill an aneurysm; and

an outer element coaxially surrounding the intermediate element and in intimate contact therewith, the outer element defining a gap or opening through which the intermediate element is exposed;

wherein the inner element has proximal and distal ends, and wherein the outer element comprises an open-wound helical coil portion extending between proximal and distal end sections that are respectively attached to the inner element adjacent to the proximal and distal ends of the inner element, wherein the open-wound portion defines the gap or opening.

41. (Previously Presented) The vaso-occlusive device of claim 40, wherein the inner element comprises a microcoil made of a biocompatible material selected from the group consisting of metal wire and polymeric filament.

42. (Previously Presented) The vaso-occlusive device of claim 40, wherein the intermediate element includes an expansile polymeric material

43. (Previously Presented) The vaso-occlusive device of claim 40, wherein the outer element includes an open-wound, helically-coiled portion that defines the gap or opening through which the intermediate element is exposed.

44. (Previously Presented) The vaso-occlusive device of claim 40, wherein the inner element has proximal and distal ends, and wherein the device further comprises a coupling element attached to the proximal end.

45. (Previously Presented) The vaso-occlusive device of claim 42, wherein the expansile polymeric material consists essentially of a hydrogel.

46. (Previously Presented) The vaso-occlusive device of claim 45, wherein the hydrogel is of a type that expands in response to a change in an environmental parameter.

47. (Previously Presented) The vaso-occlusive device of claim 46, wherein the environmental parameter is selected from the group consisting of temperature and pH.

48. (Previously Presented) The vaso-occlusive device of claim 40, wherein the intermediate element, when expanded, extends through the openings of the outer element to form an exterior surface having an undulating configuration defining a chain of convexly-curved arcuate segments.

49. (Previously Presented) The vaso-occlusive device of claim 40, wherein the proximal end section of the outer element includes a close-wound helical coil section.

50. (Previously Presented) The vaso-occlusive device of claim 40, wherein each of the proximal and distal end sections of the outer element includes a close-wound helical coil section.

51. (Previously Presented) The vaso-occlusive device of claim 49, further comprising a coupling element attached to the proximal end of the inner element and to the proximal end section of the outer element.

52. (Previously Presented) A vaso-occlusive device comprising:

first, second, and third elongate, flexible elements arranged coaxially, wherein the first element is a filamentous inner element, the second element is an expansile intermediate element capable of expanding at a controlled rate to fill an aneurysm, and the third element is an outer element having an opening or gap through which the intermediate element is exposed, and wherein at least one of the inner and intermediate elements is made at least in part of a non-metallic biocompatible material

wherein the inner element has proximal and distal ends, and wherein the outer element comprises an open-wound helical coil portion extending between proximal and distal end sections that are respectively attached to the inner element adjacent to the proximal and distal ends of the inner element, wherein the open-wound portion defines the opening or gap.

53. (Previously Presented) The vaso-occlusive device of claim 52, wherein the biocompatible material includes a bioactive agent.

54. (Previously Presented) The vaso-occlusive device of claim 52, wherein the biocompatible material includes a therapeutic compound.

55. (Previously Presented) The vaso-occlusive device of claim 52, wherein the inner element comprises a microcoil made of a biocompatible material selected from the group consisting of metal wire and polymeric filament, and wherein the intermediate element is formed of a biocompatible polymeric material

56. (Previously Presented) The vaso-occlusive device of claim 52, wherein the intermediate element includes an expansile polymeric material

57. (Previously Presented) The vaso-occlusive device of claim 52, wherein the outer element includes an open-wound, helically-coiled portion that defines the opening or gap through which the intermediate element is exposed.

58. (Previously Presented) The vaso-occlusive device of claim 52, wherein the inner element has proximal and distal ends, and wherein the device further comprises a coupling element attached to the proximal end.

59. (Previously Presented) The vaso-occlusive device of claim 56, wherein the expansile polymeric material consists essentially of a hydrogel.

60. (Previously Presented) The vaso-occlusive device of claim 59, wherein the hydrogel is of a type that expands in response to a change in an environmental parameter.

61. (Previously Presented) The vaso-occlusive device of claim 60, wherein the environmental parameter is selected from the group consisting of temperature and pH.

62. (Previously Presented) The vaso-occlusive device of claim 52, wherein the intermediate element, when expanded, extends through the opening or gap of the outer element to form an exterior surface having an undulating configuration defining a chain of convexly-curved arcuate segments.

63. (Previously Presented) The vaso-occlusive device of claim 52, wherein the proximal end section of the outer element includes a close-wound helical coil section.

64. (Previously Presented) The vaso-occlusive device of claim 52, wherein each of the proximal and distal end sections of the outer element includes a close-wound helical coil section.

65. (Previously Presented) The vaso-occlusive device of claim 63, further comprising a coupling element attached to the proximal end of the inner element and to the proximal end section of the outer element.

66. (Previously Presented) A vaso-occlusive device comprising:

an expansile first member capable of expanding at a controlled rate to fill an aneurysm having an expanded diameter;

a second member helically surrounding the first member, the second member having a diameter smaller than the expanded diameter of the first member, such that portions of the first member expand through coils of the second member when the device is released in a vasculature.

67. (Previously Presented) A vaso-occlusive device comprising:

an open-coiled element;

a expansile element capable of expanding at a controlled rate to fill an aneurysm and having a first state and a second state wherein:

in said first state said expansile element does not extend through openings between coils of the open-coiled element;

in said second state said expansile element is expanded through said openings between said coils of the open-coiled element.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.